

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT TRANSMITTAL

Re Application of: Hill et al.

For: CLOSED LOOP NEUROMODULATION FOR PREVENTION AND TREATMENT OF CARDIAC CONDITIONS

Serial No.: 10/035,319

Filed: 10/26/2001

CERTIFICATE OF MAILING UNDER 37 CFR 1.8: I hereby certify that this **MISSING PARTS** and the paper(s), as described herein, are being deposited in the U.S. Postal Service, as first class mail, addressed to the Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 21st day of March, 2006.

Molly Chlebeck
Signature
Molly Chlebeck
Printed Name

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

We are transmitting herewith the attached:

- ☐ Information Disclosure Statement
- ☒ Supplemental Information Disclosure Statement
- ☒ PTO FORM 1449
- ☒ Copies cited references
- ☒ Return Postcard

FEE CALCULATION

- ☒ \$ 00.00 Pursuant to 37 CFR §1.97(b) (before mailing of first Office Action)
- ☐ \$ 00.00 Pursuant to 37 CFR §1.97(c) with Certification (cited in foreign application not more than 3 months earlier)
- ☐ \$ 00.00 Pursuant to 37 CFR §1.97(e) with Certification
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- ☐ \$180.00 Pursuant to 37 CFR §1.97(d) with Certification

- ☐ Applicant hereby petitions for a _____ months' extension of time. If an additional extension of time is required, please consider this petition therefor.
- ☒ Applicant believes that no extension of time is required. However, if an extension of time is required, please consider this a petition therefor to provide for the possibility that applicant has inadvertently overlooked the need for an extension of time.
- ☒ Please charge any additional fees or credits to Deposit Account No. 13-2546 which may have been overlooked with regard to this filing. A duplicate of this transmittal is enclosed.

20 March 06
Date

Paul H. McDowall
Paul H. McDowall
Reg. No. 34,873
Telephone: (763) 514-3351
Customer No. 27581



Docket: P10124.00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Hill et al.)	Art Unit: 3766
)	
Serial No.: 10/035,319)	Examiner: F. Oropeza
)	
Filed: October 26, 2001)	

For: CLOSED LOOP NEUROMODULATION FOR PREVENTION AND TREATMENT
OF CARDIAC CONDITIONS

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington D.C. 20231

Dear Sir:

In compliance with the duty imposed by 37 C.F.R. § 1.56, and in accordance with C.F.R. §§ 1.97 *et. seq.*, the materials enclosed herewith are brought to the attention of the Examiner as possibly being of interest in connection with the above-identified patent application.

Consideration of each of the documents listed on the attached Form 1449 is respectfully requested. Pursuant to the provisions of M.P.E.P. §609, Applicant further requests that a copy of the Form 1449, marked as being considered and initialed by the Examiner, be returned with the next Official Communication.

Respectfully submitted,

Date

20 March 06

By:

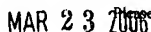
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
				Application Number	10/035,319
				Filing Date	October 26, 2001
				First Named Inventor	Thomas J. Mullen
				Group Art Unit	3762
				Examiner Name	F. Oropeza
				Attorney Docket Number	P10124.00
Sheet	2	of	5		

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite ¹ No.	Foreign Patent Document			Name of Patentee of Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T°
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
	BR		WO 9216257	A1	Obel, et al.	10-01-1992		
	BS		EP 0530354	A1	Obel, et al.	03-10-1993		
	BT		EP 0547734	A2	Collins	06-23-1993		
	BU		EP 0721786	A2	Obel, et al.	07-17-1996		
	BV		WO 9955413	A1	King	11-04-1999		
	BW		WO 0234327	A2	Mullen, et al.	05-02-2002		
	BX		WO 0234330	A2	Hill, et al.	05-02-2002		
	BY		WO 0245791	A2	Hill, et al.	06-13-2002		
	BZ		WO 2002085448	A2	Foreman, et al.	10-31-2002		
	CA		WO 2003099377	A1	Ayal, et al.	12-04-2003		

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite ¹ No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CB	LI, et al., "Reversal of Reflex-Induced Myocardial Ischemia by Median Nerve Stimulation (A): A Feline Model of Electroacupuncture," dated March 31, 1998, pp. 1186-94	
	CC	HORSCH, et al., "Spinal Cord Stimulation For Ischemic Rest Pain," from <u>The Belgian Randomized Study</u> , dated 1994, pp. 197-201	
	CD	BILGUTAY, et al., "Vagal Tuning," from <u>Journal of Thoracic & Cardiovascular Surgery</u> , July 1968, 56:71-82	
	CE	BRAUNWALD, et al., "Carotid Sinus Nerve Stimulation in the Treatment of Angina Pectoris and Supraventricular Tachycardia," from <u>California Medicine, The Western Journal of Medicine</u> , March 1970, 112(3):41-50	
	CF	ARMOUR, "Instant-to-Instant Reflex Cardiac Regulation," 1976, 309-328	
	CG	SCHWARTZ, et al., "Effect of dorsal root section on the arrhythmias associated with coronary occlusion," from <u>American Journal of Physiology</u> , September 1976, pp. 923-928	
	CH	BLAIR, et al., "Responses of Thoracic Spinothalamic Neurons to Intracardiac Injection of Bradykinin in the Monkey," from <u>Circulation Research</u> Vol. 51, No. 1, July 1982, pp. 83-94	
	CI	AMMONS, et al., "Vagal Afferent Inhibition of Spinothalamic Cell Responses to Sympathetic Afferents and Bradykinin in the Monkey," from <u>Circulation Research</u> , Vol. 53, No. 5, November 1983, pp. 603-612	
	CJ	BLAIR, et al., "Responses of Thoracic Spinothalamic and Spinoreticular Cells to Coronary Artery Occlusion," from <u>Journal of Neurophysiology</u> , Vol. 51, No. 4, April 1984, pp. 636-648	
	CK	AMMONS, et al., "Effects of intracardiac bradykinin on T ₂ – T ₃ medial spinothalamic cells," from <u>American Journal of Physiology</u> , 1985, pp. R147-R152	
	CL	BLAIR, et al., "Activation Of Feline Spinal Neurons By Potentiated Ventricular Contractions And Other Mechanical Cardiac Stimuli," from <u>Journal of Physiology</u> , 1988, pp. 649-667	
	CM	SCHWARTZ, et al., "Autonomic Mechanisms And Sudden Death – New Insights From Analysis Of Baroreceptor Reflexes In Conscious Dogs With And Without A Myocardial Infarction," from <u>Circulation</u> , Vol. 78, No. 4, October 1988, pp. 970-979	
	CN	HOBBS, et al., "Cardiac And Abdominal Vagal Afferent Inhibition Of Primate T ₉ – S ₁ Spinothalamic Cells," from <u>The American Physiological Society</u> , 1989, pp. R889-R895	
	CO	BUTLER, et al., "Cardiac Responses To Electrical Stimulation Of Discrete Loci In Canine Atrial And Ventricular Ganglionated Plexi," from <u>The American Physiological Society</u> , 1990, pp. H1365-H1373	

Examiner Signature	Date Considered	
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		Group Art Unit	3762
		Examiner Name	F. Oropeza
		Attorney Docket Number	P10124.00
Sheet	3	of	5

CP	HULL, et al., "Heart Rate Variability Before And After Myocardial Infarction In Conscious Dogs At High And Low Risk Of Sudden Death," from <u>The American College of Cardiology</u> , 1990, pp. 978-985
CQ	ARMOUR, M.D., "Intrinsic Cardiac Neurons," from <u>Journal of Cardiovascular Electrophysiology</u> , Vol. 2, No. 4, August 1991, pp. 331-341
CR	CHANDLER, et al., "Effects Of Vagal Afferent Stimulation On Cervical Spinothalamic Tract Neurons In Monkeys," from <u>Pain</u> , 1991, pp. 81-87
CS	LINDEROTH, M.D., et al., "Effects Of Sympathectomy On Skin And Muscle Microcirculation During Dorsal Column Stimulation: Animal Studies," from <u>Neurosurgery</u> , Vol. 29, No. 6, 1991, pp. 874-879
CT	VANOLI, et al., "Vagal Stimulation And Prevention Of Sudden Death In Conscious Dogs With A Healed Myocardial Infarction," from <u>Circulation Research</u> , Vol. 68, No. 5, May 1991, pp. 1471-1481
CU	CARDINAL, et al., "Distinct Activation Patterns Of Idiopathic Rhythms And Sympathetically-Induced Ventricular Tachycardias In Dogs With Atrioventricular Block," from <u>PACE</u> , September 1992, pp. 1300-1306
CV	FU, et al., "Vagal Afferent Fibers Excite Upper Cervical Neurons And Inhibit Activity Of Lumbar Spinal Cord Neurons In The Rat," from <u>Pain</u> , 1992, pp. 91-100
CW	HOBBS, et al., "Evidence That C ₁ and C ₂ Propriospinal Neurons Mediate The Inhibitory Effects Of Viscerosomatic Spinal Afferent Input On Primate Spinothalamic Tract Neurons," from <u>Journal of Neurophysiology</u> , Vol. 67, No. 4, April 1992, pp. 852-860
CX	HOBBS, et al., "Segmental Organization Of Visceral And Somatic Input Onto C ₃ - T ₆ Spinothalamic Tract Cells Of The Monkey," from <u>Journal of Neurophysiology</u> , Vol. 68, No. 5, November 1992, pp. 1575-1588
CY	CHANDLER, et al., "A Mechanism Of Cardiac Pain Suppression By Spinal Cord Stimulation: Implications For Patients With Angina Pectoris," from <u>European Heart Journal</u> , 1993, pp. 96-105
CZ	HUANG, et al., "Effects Of Transient Coronary Artery Occlusion On Canine Intrinsic Cardiac Neuronal Activity," from <u>Integrative Physiological and Behavioral Science</u> , Vol. 28, No. 1, January-March 1993, pp. 5-21
DA	ADAMSON, et al., "Unexpected Interaction Between β -Adrenergic Blockage And Heart Rate Variability Before And After Myocardial Infarction - A Longitudinal Study In Dogs At High And Low Risk For Sudden Death," from <u>American Heart Association, Inc.</u> , 1994, pp. 976-382
DB	ARDELL, "Structure And Function Of Mammalian Intrinsic Cardiac Neurons," from <u>Neurocardiology</u> , 1994, pp. 95-114
DC	ARMOUR, "Peripheral Autonomic Neuronal Interactions In Cardiac Regulation," from <u>Neurocardiology</u> , 1994, pp. 219-244
DD	FOREMAN, "Spinal Cord Neuronal Regulation Of The Cardiovascular System," from <u>Neurocardiology</u> , 1994, pp. 245-276
DE	HULL, et al., "Exercise Training Confers Anticipatory Protection From Sudden Death During Acute Myocardial Ischemia," from <u>Circulation</u> , 1994, pp. 548-552
DF	LINDEROTH, et al., "Sympathetic Mediation Of Peripheral Vasodilation Induced By Spinal Cord Stimulation: Animal Studies Of The Role Of Cholinergic And Adrenergic Receptor Subtypes," from <u>Neurosurgery</u> , Vol. 35, No. 4, October 1994, pp. 711-719
DG	YUAN, et al., "Gross And Microscopic Anatomy Of The Canine Intrinsic Cardiac Nervous System," from <u>The Anatomical Record</u> , 1994, pp. 75-87
DH	ARMOUR, "Canine Intrinsic Cardiac Neurons Involved In Cardiac Regulation Possess a ₁ , a ₂ , b ₁ and b ₂ Adrenoreceptors," from <u>Can. J. Physiol. Pharmacol.</u> , 1996, pp. 277-284
DI	CARDINAL, et al., "Reduced Capacity Of Cardiac Efferent Sympathetic Neurons To Release Noradrenaline And Modify Cardiac Function In Tachycardia-Induced Canine Heart Failure," from <u>Can. J. Physiol. Pharmacol.</u> , 1996, pp. 1070-1078
DJ	CHANDLER, et al., "Vagal, Sympathetic And Somatic Sensory Inputs To Upper Cervical (C ₁ -C ₃) Spinothalamic Tract Neurons In Monkeys," from <u>The American Physiological Society</u> , 1996, pp. 2555-2567
DK	ZHANG, et al., "Thoracic Visceral Inputs Use Upper Cervical Segments To Inhibit Lumbar Spinal Neurons In Rats," from <u>Brain Research</u> , 1996, pp. 337-342
DL	ARMOUR, et al., "Gross And Microscopic Anatomy Of The Human Intrinsic Cardiac Nervous System," from <u>The Anatomical Record</u> , 1997, pp. 289-298

Examiner Signature	Date Considered
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<p>Substitute for form 1449A/PTO</p> <p style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</p> <p style="text-align: center;">(use as many sheets as necessary)</p>		<p style="text-align: center;">Complete if Known</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Application Number</td> <td>10/035,319</td> </tr> <tr> <td>Filing Date</td> <td>October 26, 2001</td> </tr> <tr> <td>First Named Inventor</td> <td>Thomas J. Mullen</td> </tr> <tr> <td>Group Art Unit</td> <td>3762</td> </tr> <tr> <td>Examiner Name</td> <td>F. Oropeza</td> </tr> <tr> <td>Attorney Docket Number</td> <td>P10124.00</td> </tr> </table>		Application Number	10/035,319	Filing Date	October 26, 2001	First Named Inventor	Thomas J. Mullen	Group Art Unit	3762	Examiner Name	F. Oropeza	Attorney Docket Number	P10124.00
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Sheet	4	of	5												

	DM	CROOM, et al., "Cutaneous Vasodilation During Dorsal Column Stimulation Is Mediated By Dorsal Roots And CGRP," from <u>The American Physiological Society</u> , 1997, pp. H950-H957	
	DN	HAUTVAST, et al., "Spinal Cord Stimulation In Chronic Intractable Angina Pectoris: A Randomized, Controlled Efficacy Study," from <u>American Heart Journal</u> , Vol. 136, No. 6, 1998, pp. 1114-1120	
	DO	SCHWARTZ, et al., "Autonomic Mechanisms And Sudden Death - New Insights From Analysis Of Baroreceptor Reflexes In Conscious Dogs With And Without Myocardial Infarction," from <u>Circulation</u> , Vol. 78, No. 4, October 1988, pp. 969-979	
	DP	BARRON, et al., "Spinal Integration Of Antidromic Mediated Cutaneous Vasodilation During Dorsal Spinal Cord Stimulation In The Rat," from <u>Neuroscience Letter</u> , 1999, pp. 173-176	
	DQ	FOREMAN, "Mechanisms Of Cardiac Pain," from <u>Annu. Rev. Physiol.</u> , 1999, pp. 143-167	
	DR	LINDEROTH, et al., "Physiology Of Spinal Cord Stimulation: Review And Update," from <u>Neuromodulation</u> , Vol. 2, No. 3, 1999, pp. 150-164	
	DS	QIN, et al., "Chemical Activation Of Cervical Cell Bodies: Effects On Responses To Colorectal Distension In Lumbosacral Spinal Cord Of Rats," from <u>The American Physiological Society</u> , 1999, pp. 3423-3433	
	DT	CHANDLER, et al., "Intrapericardiac Injections Of Algogenic Chemicals Excite Primate C ₁ - C ₂ Spinothalamic Tract Neurons," from <u>The American Physiological Society</u> , 2000, pp. R560-R568	
	DU	FOREMAN, et al., "Modulation Of Intrinsic Cardiac Neurons By Spinal Cord Stimulation: Implications For Its Therapeutic Use In Angina Pectoris," from <u>Cardiovascular Research</u> , 2000, pp. 367-375	
	DV	HOPKINS, et al., "Pathology Of Intrinsic Cardiac Neurons From Ischemic Human Hearts," from <u>The Anatomical Record</u> , 2000, pp. 424-436	
	DW	KEMBER, et al., "Aperiodic Stochastic Resonance In A Hysteretic Population Of Cardiac Neurons," from <u>The American Physical Society</u> , 2000, pp. 1816-1824	
	DX	MEYERSON, et al., "Spinal Cord Stimulation," from <u>Bonica's Management of Pain</u> , 2001, pp. 1857-1876	
	DY	ARDELL, "Neurohumoral Control Of Cardiac Function," from <u>Heart Physiology and Pathophysiology</u> , Fourth Edition, 2001, pp. 45-59	
	DZ	FARRELL, et al., "Angiotensin II Modulates Catecholamine Release Into Interstitial Fluid Of Canine Myocardium In Vivo," from <u>Am J. Physiol. Heart Cir. Physiol.</u> , 2001, pp. H813-H822	
	EA	KINGMA, JR., et al., "Neuromodulation Therapy Does Not Influence Blood Flow Distribution Or Left-Ventricular Dynamics During Acute Myocardial Ischemia," from <u>Autonomic Neuroscience: Basic & Clinical</u> , 2001, pp. 47-54	
	EB	TANAKA, et al., "Low Intensity Spinal Cord Stimulation May Induce Cutaneous Vasodilation Via CGRP Release," from <u>Brain Research</u> , 2001, pp. 183-187	
	EC	QIN, et al., "Responses And Afferent Pathways Of Superficial And Deeper C ₁ -C ₂ Spinal Cells To Intrapericardial Algogenic Chemicals In Rats," from <u>The American Physiological Society</u> , December 2000, pp. 1522-1532	
	ED	ARMOUR, et al., "Long-Term Modulation Of The Intrinsic Cardiac Nervous System By Spinal Cord Neurons In Normal And Ischaemic Hearts," from <u>Autonomic Neuroscience: Basic & Clinical</u> , 2002, pp. 71-79	
	EE	CHANDLER, et al., "Spinal Inhibitory Effects Of Cardiopulmonary Afferent Inputs In Monkeys: Neuronal Processing In High Cervical Segments," from <u>J. Neurophysiol.</u> , 2002, pp. 1290-1302	
	EF	CARDINAL, et al., "Spinal Cord Activation Differentially Modulates Ischaemic Electrical Responses To Different Stressors In Canine Ventricles," from <u>Autonomic Neuroscience: Basic & Clinical</u> , 2004, pp. 37-47	
	EG	ARDELL, "Intrathoracic Neuronal Regulation Of Cardiac Function," from <u>Basic and Clinical Neurocardiology</u> , 2004, pp. 118-152	
	EH	KONSTANTINOV, et al., "electrical stimulation of the spinal cord in cardiovascular disease," from <u>Vestn Ross Akad Med Nauk</u> , 2002, pp. 17-23	
	EI	DI PEDE, et al., "Long-Term Effects Of Spinal Cord Stimulation On Myocardial Ischemia And Heart Rate Variability: Results Of A 48-Hour Ambulatory Electrocardiographic Monitoring," from <u>Ital. Heart J.</u> , September 2001, pp. 690-695	

Examiner Signature	Date Considered
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	DJ	NORRSELL, et al., "Effects Of Spinal Cord Stimulation And Coronary Artery Bypass Grafting On Myocardial Ischemia And Heart Rate Variability: Further Results From The ESBY Study," from <u>Cardiology</u> , 2000	
	DK	JESSURUN, et al., "Clinical Follow-Up After Cessation Of Chronic Electrical Neuromodulation In Patients With Severe Coronary Artery Disease: A Prospective Randomized Controlled Study On Putative Involvement Of Sympathetic Activity," from <u>Pacing Clin. Electrophysiol.</u> , 2001, pp. 1432-1439	
	DL	HAUTVAST, et al., "Effect Of Spinal Cord Stimulation On Heart Rate Variability And Myocardial Ischemia In Patients With Chronic Intractable Angina Pectoris—A Prospective Ambulatory Electrocardiographic Study," from <u>Clin. Cardiol.</u> , January 1998, pp. 33-38	
	DM	LINDEROTH, et al., "Preemptive Spinal Cord Stimulation Reduces Ischemia In An Animal Model Of Vasospasm," from <u>Neurosurgery</u> , August 1995, pp. 271-272	
	DN	ELIASSON, et al., "Safety Aspects Of Spinal Cord Stimulation In Severe Angina Pectoris," from <u>Coron. Artery Dis.</u> , October 1994, pp. 845-850	
	DO	PIVOVAROV, et al., "Effect Of Electrostimulation Of The Dorsolateral Funiculus Of The Spinal Cord On Changes In The Cardiac Rhythm In Acute Myocardial Ischemia," from <u>Biull Edsp. Biol. Med.</u> [Russian] December 1985, pp. 655-657	
	DP	KRYZHANOVSKI, et al., "Characteristics Of The Rhythmic Activity Of A Normal And A Damaged Heart During Hyperactivity Of Spinal Cord Preganglionic Neurons," from <u>Biull Edsp. Biol. Med.</u> [Russian] September 1983, pp. 14-16	
	DQ	RECORDATI, et al., "Renorenal Reflexes In The Rat Elicited Upon Stimulation Of Renal Chemoreceptors," from <u>J. Auton. Nerv. Syst.</u> , September 1982, pp. 127-142	

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